UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,218	08/03/2001	Barbara Horsey O'Connor	7010-0018	7233

7590 01/26/2004

ROBINS & PASTERNAK LLP
Suite 200
90 Middlefield Road
Menlo Park, CA 94025

EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,218	O'CONNOR ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-87* is/are pending in the application.

4a) Of the above claim(s) *39-63 and 72-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-71 and 81-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/3/03 & 11/3/03
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The examiner acknowledges receipt of the amendment and IDS filed 11/3/03 and IDS filed 7/3/03.

Specification

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 64-71, 81-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Ponti et al. (GB 2245831).

Applicants claims a method for making a powdered pharmaceutical composition, said method comprising: (a) providing a mixture of pre-formed hydrogel particles, (b) contacting the hydrogel particles with an aqueous composition containing a pharmacologically active agent for a period sufficient to allow the agent to associate with the hydrogel particles and be incorporated therewith; (c) separating the hydrogel particles form the aqueous composition...(d) contacting the primary loaded hydrogel particle with aqueous composition comprising said pharmaceutically active agent...(e) separating the hydrogel formed in step (d) form the aqueous composition in at least a partial drying step and (f) drying the secondary hydrogel particles to obtain a powered pharmaceutical composition.

De Ponti discloses formulation for treating burns or wounds comprising a powder of water-soluble and water-swellable polysaccharide microspheres loaded with a heparin-binding

growth factor. The polysaccharides include cellulose, starches, dextrans, collagen, gelatin or albumin. See abstract. The powder comprises water-soluble and water-swellable microspheres loaded with a heprin-binidng growth factor. The powder has gel-forming capability. It is typically a lyophilized powder. The microspheres are typically biodegradable. See pages 2-3. The microspheres are loaded with an amount of growth factor effective for use in treating a wound or burn. The amount may therefore be tailored to requirements. Typically, however, the microspheres are loaded with from 0.2 to 5.0 mg of growth factor per gram of microspheres. See page 5. The powder is prepared by a process which comprises: (i) soaking water-insoluble and water-swellable polysaccaride microspheres in an aqueous solution of a heparin-binding growth factor; and (ii) lyophilizing the dispersion of the microspheres in the aqueous growth factor solution. The growth factor is loaded into the microspheres by first soaking a weighed amount of microspheres in a solution of the growth factor in water. The ratio of microspheres: growth factor in solution and microspheres: solution of growth factor may vary greatly. See pages 6-7. During the soaking the microspheres reach a certain degree of swelling depending from their chemical composition, unswollen diameter, the nature of their cross-linking agent and its relative content with reference to the microspheres, temperature, pH, ionic strength, nature of the solution and presence of surface modifiers on the microspheres. The microspheres are soaked for sufficient time so that the growth factor is absorbed onto and/or into the microspheres. The time needed for soaking (incubation) can vary greatly. The time may be from 2 mins to 48 hours, preferably from 2 mins to 2 hours, at room temperature. Following the soaking step, freeze-drying is carried out to eliminate water. The type of freeze-drying is carried out to eliminate water. The type of freeze-drying process can vary greatly. Suitable results are

obtained with anything from very simple equipment, to sophisticated freeze-driers where it is possible to control various temperatures (shelfs, product, condenser), the vacuum and times. See page 8 and claims 7-9. De Ponti does not explicitly state contacting the primary loaded hydrogel particles with an aqueous composition to allow further agent to associate with the hydrogel.

It is the position of the examiner it would have been obvious to one of ordinary skill in the art at time the invention was made to have modified the composition of De Ponti by contacting the primary loaded hydrogel particles with an aqueous composition to allow further agent to associate with the hydrogel because of the expectation of obtaining the desired swelling and amount of growth factor absorbed onto and /or into the microsphere as taught by De Ponti. Both the reference and the instant application desire a powdered pharmaceutical by mixing pre-formed hydrogel particles with a pharmaceutically active agent for a period of time sufficient to allow the agent to associate with the hydrogel particles. Therefore, it would have been within the skill of the art to determine the soaking time as well as the number of times to soak the hydrogel particle in order to obtain the desired amount of agent on and/or in the hydrogel particles. One of ordinary skill in the art would achieve the desired degree of drug loading by considering such factors as the ionic strength of the aqueous solution, the temperature and drug solubility.

Response to Arguments

3. Applicant's arguments filed 11/3/03 have been fully considered but they are not persuasive.

Applicants argue De Ponti does not disclose the steps of separating the hydrogel paticles having the active agent incorporated therewith or to obtain secondary loaded hydrogel particles having the active agent incorporated therewith. It is the position of the examiner it would have

been obvious to one of ordinary skill in the art at time the invention was made to have modified the composition of De Ponti by contacting the primary loaded hydrogel particles with an aqueous composition to allow further agent to associate with the hydrogel because of the expectation of obtaining the desired swelling and amount of growth factor absorbed onto and /or into the microsphere as taught by De Ponti. Both the reference and the instant application desire a powdered pharmaceutical by mixing pre-formed hydrogel particles with a pharmaceutically active agent for a period of time sufficient to allow the agent to associate with the hydrogel particles. Therefore, it would have been within the skill of the art to determine the soaking time as well as the number of times to soak the hydrogel particle in order to obtain the desired amount of agent on and/or in the hydrogel particles. One of ordinary skill in the art would achieve the desired degree of drug loading by considering such factors as the ionic strength of the aqueous solution, the temperature and drug solubility. Therefore, the rejection is maintained.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779 (as of 2/4/04, (571) 272-0589). The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927 (as of 2/4/04, (571) 272-0602). The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600